PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B11371 PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/009242	International filing date *(day/month/year)* 02.07.2004	Priority date *(day/month/year)* 02.07.2003
International Patent Classification (IPC) or national classification and IPC G01N33/569		
Applicant NEUTRACT et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.04.2005	29.08.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Cuendet, P Telephone No. +49 89 2399-8690

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/009242

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-9 as originally filed

   Claims, Numbers

   1-10 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/009242

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-10
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	1

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1). **Preamble**

The present application relates to diagnosing an "intolerance" (i.e. "infection, inflammation and other syndromes such as food intolerance", cf. pp.2/3, bridging paragraph) due to a specific substance by incubating PMN with a "specific substance" and subsequent detection of activation; the expression "detection of activation" would encompass an "uptake" which would correspond to a binding, cf. pp.3/4, bridging paragraph.

2). **Re Item V.**

2.1. The following documents are referred to in this communication:

D1 : WO 96/40869 A (UNIV CONNECTICUT) 19 December 1996 (1996-12-19)

D2 : ABDELILAH S ET AL: "Functional expression of IL-9 receptor by human neutrophils from asthmatic donors: role in IL-8 release." JOURNAL OF IMMUNOLOGY (BALTIMORE, MD. : 1950) 15 FEB 2001, vol. 166, no. 4, 15 February 2001 (2001-02-15), pages 2768-2774, XP002298341 ISSN: 0022-1767

2.2. Lack of novelty and lack of inventive step

The present application does not meet the criteria of Article 33(1) and PCT, because the subject-matter of claims 1 and 2-10 is not new and/or not inventive in the sense of Article 33(2) and (3) PCT.

(i) It is reminded that according to the present application the expression "diagnosing intolerance" would encompass diagnosing infection and the expression "activated" would also imply binding; see in item 1 above.

Document **D1** discloses diagnosing infection by incubating PMN with a foreign substance/pathogen and the subsequent detection of a binding response of the PMN; see D1, p.8, paragraphs 1 and 2 and claims 1, 13 and 25. Thus, the present claims would appear to lack novelty or at least an inventive step regarding D1.

(ii) Document **D2** discloses that activation of PMN in asthma/allergy is dose-dependent, i.e. proportional to the seriousness of airway inflammation, see D2, p.2773, left-hand column, last paragraph. The skilled person would have known from D2 that this dose dependent situation in asthma/allergy would relate back to an allergen (**see D2, p.2772, first paragraph of discussion**), i.e. to a "specific substance" and, in the light of D1 which relates to the diagnosic use of activated PMN, would have realised a diagnostic possibility for a "specific substance" inducing an intolerance, i.e. airway inflammation. Thus, the present claims would appear to lack an inventive step regarding D1+D2.

3). **Re Item VIII.**

3.1. Present claim 1 would appear to be a diagnostic method involving a treatment of the human or animal body, i.e. relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT; cf. claim 1 "...from whole blood drawn from the subject...".

3.2. Present claim 1 would appear to lack sufficient disclosure because "diagnosing intolerance" according to claim 1 is not shown in the description; no results obtained/suitable to allow a diagnosis of intolerance by a subject can be found. Furthermore, no "specific substance" is disclosed in the description, see, e.g. in examples the terms "food", "foods". It should be noted that p.1, lines 25-31 and p.1, lines 19-24 of the present description relate to the state of the art and not to the present invention; the latter would appear to start on p.2, line 28.